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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/523,217

10/19/2005

Randolf Von Oepen

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11/12/2008

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EXAMINER

SONNETT, KATHLEEN C

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/523,217	Applicant(s) VON OEPEN ET AL.	
	Examiner KATHLEEN SONNETT	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36 and 38-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36 and 38-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/20/2008 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 50 and 51** are rejected under 35 U.S.C. 102(b) as being anticipated by Kensey et al. (U.S. 5,545,178). Kensey et al. discloses an apparatus for facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising a bar having proximal and distal ends and a first eyelet coupled to the bar (fig. 24: 202), a filament (108) having a first and second free end (fig. 24), the filament being slidably disposed through the first eyelet, the bar being slidable relative to the filament.

4. **Claims 50, 51, and 57** are rejected under 35 U.S.C. 102(b) as being anticipated by Marchand (US 6,228,096). Marchand discloses an apparatus for facilitating sealing of a puncture formed in a proximal lateral surface of a vessel, the apparatus comprising a bar having proximal and distal ends and a first eyelet coupled to the bar (100; fig. 4b), a filament ("S") having a first and second free end (fig. 7), the filament being slidably disposed through the first eyelet, the bar being slidable relative to the filament.

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5. Regarding claim 57, Marchand discloses a tensioning device configured to hold the filament in a tensioned state (col. 3 ll. 65-col. 4 ll.10).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. **Claim 56** is rejected under 35 U.S.C. 103(a) as being unpatentable over Marchand.

Marchand discloses the invention substantially but does not expressly disclose that the bar is made of a biodegradable material. However, biodegradable suture fixation members are very well known in the art and such a modification would have been obvious to one skilled in the art in order to increase biocompatibility of the device.

8. **Claims 52 and 53** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchand in view of Rollero. Marchand in view of Kim discloses the invention substantially as stated above including an eyelet as the suture attachment point on a bar but fails to disclose more than one eyelet.

9. Rollero et al. discloses that it is old and well known in the art to include a plurality of attachment points in a bar such that a filament can be securely attached to the bar (see fig. 6a and 6b). This configuration includes a bore in the central region and in the distal region when the bar is inserted using the delivery sheath of Marchand. Since Marchand uses an eyelet instead of a bore, it would have been obvious to one skilled in the art to employ a plurality of eyelets in the device of Marchand to provide the plurality of attachment points taught by Rollero et al. so that suture can be securely attached to the bar if desired.

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10. Regarding 52, Rollero et al. teaches threading the filament through the first attachment point, then through the second attachment point, and then back through the first attachment point (fig. 6c for example).

11. **Claims 54 and 55** are rejected under 35 U.S.C. 103(a) as being unpatentable over Marchand in view of Kim. Marchand discloses the apparatus substantially as stated above including a delivery sheath in which the filament and bar are disposed as well as a push rod (40; fig. 8) disposed proximal of the bar but fails to disclose a sharpened tip at the distal end.

12. However, Kim teaches that it is well known in the art to include a sharpened tip (48) on the distal end of a delivery device used to deliver a suture retaining element. The sharpened tip is tapered which facilitates its insertion into tissue and is advantageous because the same instrument can be used to both form the channel to the surgical site and deliver the sealing instrument to that site. It would have been well within the purview of one skilled in the art to use such a sharpened tip on the delivery sheath of Marchand as taught by Kim because one skilled in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

13. **Claims 36, 38-40, 44, and 48** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti (Re 36,974) in view of Kim. Bonutti discloses an apparatus for facilitating sealing of a puncture formed in a proximal later surface of a vessel, the apparatus comprising a bar having proximal and distal ends and a first bore extending laterally therethrough and a filament having first and second free ends, the filament being slidably disposed through the first bore (see fig. 20), the bar being slidable relative to the filament. Bonutti discloses a delivery sheath in which the filament and bar are disposed but fails to disclose a sharpened tip at the distal end.

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14. However, Kim teaches that it is well known in the art to include a sharpened tip (48) on the distal end of a delivery device used to deliver a suture retaining element. The sharpened tip is tapered which facilitates its insertion into tissue and is advantageous because the same instrument can be used to both form the channel to the surgical site and deliver the sealing instrument to that site. It would have been well within the purview of one skilled in the art to use such a sharpened tip on the delivery sheath of Bonutti as taught by Kim because one skilled in the art has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

15. Regarding claim 38, the device further comprises a push rod (82) disposed in the lumen proximal of the bar.

16. Regarding claim 39, the bar is cylindrical.

17. Regarding claim 40, the bar may be biodegradable (see col. 3, ll. 40-41).

18. Regarding claims 44 and 48, Bonutti discloses two bores (fig. 20). The bore (186) is being considered disposed in a central region of the bar.

19. **Claims 41-43** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti in view of Kim as applied to claim 36 above and further in view of Nash et al. (US 5,411,520).

Bonutti in view of Kim discloses the invention substantially as stated above but fails to disclose a tensioning device configured to hold the filament in a tensioned state.

20. However, Nash et al. discloses that it is old and well known in the art to include a tensioning device in devices used to facilitate the sealing of a puncture. Nash et al. discloses that such a tensioning device is necessary in order to maintain appropriate tension of the filament while the delivery sheath is removed (col. 14, ll. 29-35). The tensioning device is shown in figs. 13, 14, and 26. It comprises an upright (142) having upper and lower ends, a plurality of

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legs attached to the lower end, and a grip affixed to the upper end. The legs are being considered the two pieces defined by the slit (142D) at the lower end of (142) and the grip is the portion attached to the upper end of (142) that also has a slit (142D). Regarding claim 43, the grip comprises a V-shaped groove formed in the tensioning device formed in the flexible material of the tensioning device, which is being considered an equivalent alternative to an elastomeric material. Although the material can be plastically deformed, it would have been obvious to one skilled in the art to use an elastomeric material since one skilled in the art would have recognized the advantage of having a groove that, in its closed state with no filament therein, is thinner than the diameter of the filament in order to have a stronger grip on the filament. In order to place the filament in such a groove, a material such as an elastomeric material that can be deformed but returns back to its original configuration would have been an obvious material choice to one skilled in the art. It would have been within the purview of one skilled in the art to be able to form grips similar to the louvers with an elastomeric material. Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Bonutti to include a tensioning device as made obvious by Nash et al. in order to gain the advantage of maintaining appropriate tension of the filament while removing the delivery sheath.

21. **Claims 45-47 and 49** are rejected under 35 U.S.C. 103(a) as being unpatentable over Bonutti in view of Kim as applied to claim 36 above and further in view of Rollero et al. (US 6,506,197). Bonutti in view of Kim discloses the invention substantially as stated above including the use of either a bore or an eyelet through which a filament is threaded since Kim teaches threading a filament (14) through an eyelet (104). Kim further teaches using an eyelet and bore on the same bar (fig. 9a) so that a filament (14) may be threaded through both for additional control over the bar. Bonutti in view of Kim fails to disclose the filament slidably disposed through the first bore, then the eyelet, then back through the first bore.

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22. Rollero et al. discloses that it is old and well known in the art to include a plurality of attachment points, such as holes, in a bar such that a filament can be securely attached to the bar (see fig. 6a and 6b). This configuration includes a bore in the central region and in the distal region when the bar is inserted using the delivery sheath of Bonutti. The filament is disposed through a central bore, then a bore in a distal region of the bar, then back to the central bore in order to provide a more secure attachment of the bar to the filament (see figs. 6a-6c). It would have been obvious to one of ordinary skill in the art to employ a plurality of attachment points through which the filament is slidably disposed as made obvious by Rollero et al. in the device of Bonutti so that suture can be attached to the bar more securely if desired.

23. Regarding claim 49, Rollero et al. makes obvious a plurality of bores wherein one of the bores is in a central region and one bore is disposed in a distal region of the bar.

Response to Arguments

24. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments to the claims. It is noted that the device of Kim does disclose a filament (14) slidably disposed through the eyelet (104) on bar (100; figs. 24-26). However, the filament 14 does not have two free ends as its distal end is directly attached to bar (12).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHLEEN SONNETT whose telephone number is (571)272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS 10/27/2008

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731